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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,917

10/04/2004

Peter Muhlradt

03100215AA

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30743

7590

12/26/2008

WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.

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SUITE 340

RESTON, VA 20190

EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

12/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,917	<b>Applicant(s)</b> MUHLRADT ET AL.	
	<b>Examiner</b> ROBERT A. ZEMAN	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed on 8-25-2008 is acknowledged. Claims 1-16 are pending and currently under examination.

#### ***Claim Rejections Withdrawn***

The rejection of claims 1-11 under 35 USC § 112, second paragraph, as being rendered indefinite by merely reciting a use without any active, positive steps delimiting how this use is actually practiced is withdrawn in light of the amendment thereto.

The rejection of claims 1-11 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101 is withdrawn in light of the amendment thereto.

#### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 4-16 are rejected under 35 U.S.C. 103(a) as being obvious over Muehlradt (U.S. Patent 6,573,242).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only

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under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Muehlradt discloses a S-(2,3-dihydroxypropyl)-cysteine peptide which conforms the structure (I) as set forth in claims 1 and 6 and comprises a peptide with the sequence of SEQ ID NO:3 (see abstract). Muehlradt further discloses that said S-(2, 3-dihydroxypropyl)-cysteine peptide can be used as a vaccine adjuvant (see column 2, lines 6-7).

Muehlradt differs from the instant invention in that he doesn't explicitly disclose the use of said S-(2, 3-dihydroxypropyl)-cysteine peptide as a mucosal adjuvant generally or the recited routes of administration specifically.

Given that Muehlradt discloses that said S-(2, 3-dihydroxypropyl)-cysteine peptide can be used as a vaccine adjuvant and that the use of mucosal adjuvants is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use

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the S-(2, 3-dihydroxypropyl)-cysteine peptide of Muehlradt as a mucosal adjuvant (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). Moreover, the specific routes of administration and the types of antigens, carriers etc. set forth in the instant claims were also known in the art and would be equally obvious to the skilled artisan.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being obvious over Muhlradt et al. (Journal of Experimental Medicine, 1997, Vol. 185 No. 11, pages 1951-1958 – IDS filed on 4-12-2005).

Muhlradt et al. disclose a macrophage stimulator lipopeptide from *Mycoplasma fermentans* (MALP-2) which is an S-(2, 3-bisacyloxypropyl)cysteine-peptide wherein the peptide has the sequence of SEQ ID NO:3 (see abstract). Muhlradt et al. further disclose that MALP-2 is one of the most potent natural macrophage stimulators besides endotoxins (see abstract).

Muhlradt et al. differs from the instant invention in that he doesn't explicitly disclose the use of MALP-2 as a mucosal adjuvant generally or the recited routes of administration specifically.

Given that Muhlradt discloses that MALP-2 is one of the most potent natural macrophage stimulators besides endotoxins and the fact that the use of endotoxins as mucosal adjuvants is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use the MALP-2 of Muhlradt et al. as a mucosal adjuvant (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). Moreover, the specific routes of

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administration and the types of antigens, carriers etc. set forth in the instant claims were also known in the art and would be equally obvious to the skilled artisan.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am - 5:30 p.m. .

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/  
Primary Examiner, Art Unit 1645